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Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 5,817,028 ("Application") was filed on December 3, 2010, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, ARIDOL® (mannitol), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act (FFDCA), or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would **not** be eligible for extension of the patent term under 35 U.S.C. § 156.

One of the eligibility requirements, 35 U.S.C. § 156(a)(5)(A), is that the permission for commercial marketing or use of the product must be the **first** permitted commercial marketing or use of the "product" under the provision of law under which such regulatory review period occurred. The definition of "product" is explicitly set forth in the statute at subsection (f). There, the statute defines "product" as "drug product" and in turn defines "drug product" as "the active ingredient of a new drug, . . . including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient." See § 156(f)(2). Thus, the relevant inquiry is whether the active ingredient of ARIDOL®, i.e., mannitol, is the first permitted commercial marketing or use of mannitol as reviewed under section 505 of the FFDCA. Based on Applicant's disclosures and information obtained from DRUGS@FDA,[1] , the USPTO finds that the permission to commercially market or use ARIDOL® does not constitute the first permitted commercial marketing or use of mannitol.

Applicant notes that the active ingredient of ARIDOL® is mannitol. Application at 3-4. Applicant also notes that aqueous formulations of mannitol have been previously approved under section 505 of the FFDCA. Application at page 6-7. FDA records also indicate that various

[1]http://www.accessdata.fda.gov/scripts/cder/drugsatfda/

formulations of mannitol have been approved prior to the approval of ARIDOL®. See, e.g., approval information of RESECTISOL, attachment 1. Since it is apparent that the permission to commercially market and use mannitol formulated in the drug product ARIDOL® does **not** constitute the first permitted commercial marketing or use of mannitol, U.S. Patent No. 5,817,028 is **not** eligible for extension. Please confirm that the USPTO is correct in their assessment of compliance with the requirements of 156(a)(5)(A) regarding the permission for commercial marketing or use of ARIDOL® on October 5, 2010.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Rudy Ng
Bozicevic, Field & Francis LLP
1900 University Avenue, Suite 200
East Palo Alto, Ca 94303

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Drug Details

Drug Name(s)	**RESECTISOL (Brand Name Drug)**
FDA Application No.	**(NDA) 016704**
Active Ingredient(s)	**MANNITOL**
Company	**B BRAUN**
Original Approval or Tentative Approval Date	**November 18, 1969**
Chemical Type	**5 New manufacturer**
Review Classification	**S Standard review drug**

- **There are no Therapeutic Equivalents**
- **Labels are not available**
- **Approval History, Letters, Reviews, and Related Documents**

Products on Application (NDA) #016704
Click on a column header to re-sort the table:

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
RESECTISOL	MANNITOL	5GM/100ML	SOLUTION; IRRIGATION	Discontinued	No	None

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